

MAY - 7 2004

K032400

510(k) Summary of Safety and Effectiveness

510(k) Summary This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 C.F.R. § 807.92.

Submitter Vision Pro LLC
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Opelousas, LA 70570

Contact Person Julie Powell
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Date Prepared April 7, 2004

Name of device LaFaci™ Surgical System

Classification Names Apparatus, air handling, room

Device Classification Regulatory Class: II
Product Code: FYD
Classification Panels: General & Plastic Surgery
Regulation Number: 21 C.F.R. 878.5070

**Predicate
Device(s)**

510(k) Number	Device	Manufacturer
K924732 or K924731	Dell PlumeSafe and Plume Aspiration fixation Ring Handpiece (PlumeSafe 601 or 1201)	Buffalo Filter / Asico
Unknown	Visx Star 3 Plume Evacuation	Visx, Inc.
K911808	Accurus Surgical System	Alcon Laboratories
K935218	Schuco-Vac Model 178 Aspirator	Schuco, Inc.
Exempt	Slade LASIK Aspiration Lid Speculum	ASICO
Exempt	Kritzinger-Udegraf LASIK Irrigation Cannula- 16 guage	ASICO
K963434	Continuous Fluid Air Exchange	Escalon Trek Medical
K852649	Regulator, pressure, gas cylinder	C.R.Bard
Exempt	Gimble-Chayet LASIK Drain	Katina
Exempt	Melki Lasik Flap Stabilizer	Rhein Medical Inc.
Exempt	Maldonado LASIK Posterior Ablation Platform	Rhein Medical, Inc.
Exempt	Kraff Nasal Solid Blade Speculum	ASICO
Exempt	Whitten LASIK Fixation Ring	ASICO

**Device
Description**

LaFaci™ Surgical System combines multiple functions commonly utilized during LASIK into a single hand piece allowing for the delivery of sterile balanced saline irrigation solution to the surgical field, fluid aspiration from the surgical field, delivery of micro-filtered air to the surgical field, and plume evacuation from the surgical field. All of these functions are generated and delivered from the LaFaci™ Surgical Cart to the LaFaci™ Handpiece through four-lumen surgical tubing.

LaFaci™ Handpiece also provides manual ocular fixation, and provides a platform for the temporary placement of the corneal flap during ablation. In addition the platform can be manually pivoted over the corneal bed thereby providing a spatula means to reposition the flap onto the stromal bed.

The LaFaci™ Surgical Cart accessories include an adjustable instrument tray, and handpiece tubing swing arm that provides sterile setup and operational efficiency during surgery. The LaFaci™ Surgical Cart disposable accessories include the LaFaci

Handpiece Tubing Set (sterile) and the LaFaci Smoke/Fluid Evacuation Accessories (non-sterile).

**Indications
for Use**

The LaFaci Surgical System is intended for use during LASIK procedures. The LaFaci Surgical System consists of a reusable Handpiece, Surgical Cart, and disposable Tubing Accessories. The LaFaci System provides ocular fixation and containment of surgical field, corneal flap placement and flap re-positioning, and is used for ophthalmic plume aspiration, irrigation, fluid aspiration, and the delivery of micro filtered air to the surgical field.

**Nonclinical
Performance**

The materials with patient contact are biocompatible. Bench testing of the Handpiece and the plume evacuation, irrigation, aspiration, and air delivery functions have been tested and determined to be acceptable. The LaFaci Surgical System will comply with UL 60601-1 and EN 60601-1-1-2 electrical testing.

Clinical

Performance No clinical performance data was required or performed.

Conclusion The LaFaci Surgical System is substantially equivalent to the predicate devices that are currently being marketed.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 7 2004

Emergo Group, Inc.
C/O Julie Powell
Senior Consultant
2519 McMullen Booth Road
Suite 510-295
Clearwater, FL 33761

Re: K032400

Trade/Device Name: LaFaci Surgical System
Regulation Number: 21 CFR 878.5070
Regulation Name: Air-handling apparatus for a surgical operating room
Regulatory Class: Class II
Product Code: FYD
Dated: August 4, 2003
Received: August 8, 2003

Dear Ms. Powell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

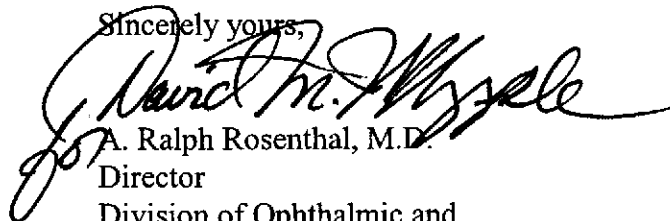
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forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "A. Ralph Rosenthal, M.D.", written over the typed name.

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and
Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K032400

Device Name: LaFaci Surgical System

Indications for Use:

The LaFaci Surgical System is intended for use during LASIK procedures. The LaFaci Surgical System consists of a reusable Handpiece, Surgical Cart, and disposable Tubing Accessories. The LaFaci System provides ocular fixation and containment of surgical field, corneal flap placement and flap re-positioning, and is used for ophthalmic plume aspiration, irrigation, fluid aspiration, and the delivery of micro filtered air to the surgical field.

(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devices

510(k) Number K032400

510(k) Number R. Butten

Prescription Use ✓
(Per 21 CFR 801.109)

OR Over the Counter
Use _____